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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/826,189	04/16/2004	Patrick Scholten	P10670.01	9794
27581	7590	07/12/2005	EXAMINER	
MEDTRONIC, INC. 710 MEDTRONIC PARKWAY NE MS-LC340 MINNEAPOLIS, MN 55432-5604			ALTER, ALYSSA M	
			ART UNIT	PAPER NUMBER
			3762	

DATE MAILED: 07/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/826,189

Applicant(s)

SCHOLTEN ET AL.

Examiner

Alyssa M. Alter

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 5 April 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-54 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-54 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 April 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

Applicant's arguments, see page 4, filed April 5, 2005, have been fully considered but they are not persuasive. The Applicant argues that Wohlgemuth does not disclose whether a paced pulse captures the heart based on morphological characteristics. However, Wohlgemuth does disclose the use of "P wave processing either for rate control, capture detection"(col. 4, line 61) in an implantable pacemaker. Capture of a stimulation pulse results in a evoked response subsequent to a stimulation pulse. The evoked response is a variation in baseline voltage or amplitude. Both voltage and amplitude are morphological signals since the effect the structure of the baseline. Therefore, Wohlgemuth inherently discloses capture detection based on a morphological signal.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the use of DSP for determining capture or loss of capture) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Double Patenting

Claims 1-54 of this application conflict with claims 1-48 of Application No. 10/424,538 (US Patent Publication 20040215276 A1). 37 CFR 1.78(b) provides that when two or more applications filed by the same applicant contain conflicting claims,

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elimination of such claims from all but one application may be required in the absence of good and sufficient reason for their retention during pendency in more than one application. Applicant is required to either cancel the conflicting claims from all but one application or maintain a clear line of demarcation between the applications. See

MPEP § 822

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

1. Claims 1-54 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-48 of copending Application No. 10/424,538 (US Patent Publication 20040215276 A1). This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless,—

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1-11, 14-21, 24-39, 42-49 and 53-54 are rejected under 35 U.S.C. 102(b) as being anticipated by Wohlgemuth (US 6,029,087). Wohlgemuth discloses an implantable cardiac pacing system having an enhanced capability of classifying intracardiac signals with digital signal processing (DSP) and software algorithms.

As to claims 1-3, 25-31 and 53, figure 1 is a functional block diagram of an implantable pacemaker that shows the primary components, including the controller 34, DSP chip 36, microprocessor 30 and electrodes 50-52 and 59-60 are used for sensed signal processing. The controller 34, which the examiner considers the pulse generator, "triggers output pulses to be generated and delivered from output stage 35"(col. 4, lines 30-31). The DSP chip 36, as seen in figure 2A, comprises an amplifier 62 and A/D converter for generating a digital signal. "Electrodes 50 and 51 which are employed both for delivery of pacing pulses and for sensing of cardiac signals"(col. 4, lines 35-36) are "located on the distal tip end of an endocardial lead 50L"(col. 4, lines 37-38).

The cardiac signals sensed, or "sense signals, are inputted to DSP block 36, which comprises a number of signal processing channels corresponding to signals of interest. For example, in a dual chamber pacemaker which incorporates P wave processing either for rate control, capture detection or any other reason, there are three channels for respective signal processing of the P, R and T waves. The data resulting from the digital signal processing is transmitted via bus 60 through controller 34 and bus 46 to microprocessor 30, for the signal classification operations, as well as any other necessary calculations"(col. 4, lines 57-67). Also, "the classification algorithms for processing the parameters generated by each DSP channel can be re-programmed in a

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known manner”(col. 5, lines 12-15). Therefore, since the microprocessor 30 processes the P wave for capture detection, it inherently detects a morphological characteristic and compares to a morphological criteria in order to determine if the pacing has been captured.

As to claims 4-11, 14-21, 24, 32-39 and 42-49, the morphological characteristics or parameters, min voltage, max voltage, min slope, max slope, time of min voltage, time of max voltage, time of min slope and time of max slope, can be derived from the DSP components in figure 2B and seen in figures 3A and 3B. “Referring now to FIG. 3A, the upper curve represents the filtered signal (SIG), and the lower signal represents a corresponding slope (SL) signal corresponding to an event which is to be sensed and classified. For each signal, plus and minus threshold values are indicated, i.e., SIG TH+, SIG TH-, SL TH+, and SL TH-”(col. 5, lines 62-67). Since the signal (SIG and SL) is compared to a threshold, positive and negative, and in excess of the threshold, the examiner considered exceeding the threshold to be the range to which the signal is compared.

“When the analysis window is active, the SIG and SL values are operated on to obtain the signal parameters that are illustrated in FIG. 3B. Referring first to the filtered signal as illustrated in FIG. 3B, both maximum and minimum values of SIG during the analysis window are obtained; the positive value is indicated as SIGmax and the negative as SIGmin. The time from sense to SIGmax is indicated as SIG Dmax; and the time from sense to SIGmin is indicated as SIG Dmin. Likewise, referring to the SL curve, values of SLmax and SLmin are determined, and the time from sense to each is

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found, namely SL Dmax and SL Dmin. Additionally, the time from first crossing of a threshold to the last crossing of a threshold is determined as labelled W; in this example W is from the first SIG crossing of the positive threshold to the last SIG crossing of the SIG positive threshold”(col. 6, lines 13-28).

As to claim 54, “the parameters from each channel are transferred on a data bus to a microprocessor, which is software controlled to classify each sensed signal as a function of one or more of the DSP-generated parameters. The software includes a classification algorithm for each DSP channel, and each algorithm is programmable so that classification for the patient can be optimized for each signal type”(col. 2, lines 42-49).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. Claims 12-13, 22-23, 40-41 and 50-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wohlgemuth (US 6,029,087) in view of van Krieken (US 5,674,254). Wohlgemuth discloses the claimed invention except for the morphology characteristic of width of the signal. van Krieken teaches that it is known to analyze morphology in a conventional manner, which includes measuring signal width, as set forth in column 7, lines 46-52. It would have been obvious to one having ordinary skill in

the art at the time the invention was made to have modified the morphological characteristics and criteria as taught by Wohlgemuth to include measuring width as taught by van Krieken, in order to thoroughly evaluate the morphology of the signal.

As to claim 13 and 41, the modified Wohlgemuth therefore teaches the comparison of the width of the signal to a threshold and range exceeding the threshold.

Conclusion

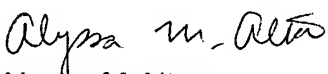

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

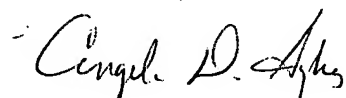
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alyssa M. Alter whose telephone number is (571) 272-4939. The examiner can normally be reached on M-F 9am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


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